DETAILED ACTION

Receipt of Applicants arguments/remarks filed on 10/19/2010 is acknowledged.

INFORMATION DISCLOSURE STATEMENT

The IDS received on 01/19/2011 has been acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-9, 11-12, 14-16, 18-20, 22-23, 28-29, and 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk, United States Patent 6,545,097, Smith et al., United States Patent, 5,639,810, and Hamilton et al., United States Patent, 6,896,842

Pinchuk et al. teach a composition for delivering therapeutic agents such as paclitaxel, see column 7, line 7 and abstract. The composition comprises a block copolymer made up of an elastomeric block and a thermoplastic block, and is used to coat at least a portion of an intravascular or intervascular medical device such as stent, see abstract and column 2, line 34. The thermoplastic polymers (high Tg block) may be used as end blocks, see column 3, lines 44-57. The elastomeric blocks can include the broad genus of polyolefin blocks. The thermoplastic blocks can include vinyl aromatic polymer blocks such as blocks of styrene (elevated Tg non siloxane unit), see column 1 lines 62-67- column 2 lines 1-3. The thermoplastic blocks (elevated Tg blocks) can comprise a mixture of two different types of Tg non siloxane units including styrene, methylstryene, acrylate blocks, vinyl aromatic blocks or mixtures thereof, see column 1, lines 62-38-column 2, lines 1-3. Pinchuk et al. teach that blends of polymers including polystyrene-polyisobutylene-polystyrene copolymers can be added with the block copolymers with the advantage of increasing the strength of the coating see column 17, lines 29-38. Though such supplemental polymers can be added in order to increase the strength of the coating, Pinchuk suggests that such polymers are an optional embodiment which is not necessarily required, see column 17, lines 29-31. Furthermore, one of ordinary skill in the art would have been motivated to leave out the supplemental carrier region in order to increase the release rate

of the therapeutic agents. The block copolymers of Pinchuk et al. can include grafting as Pinchuk et al. teach star-shaped configurations of the block copolymers, see column 3, lines 62-64. The star shaped configurations may be in B(AB)n or A(BA)n triblock configurations wherein B is the thermoplastic block and n=3 or more thus forming the star configuration (graft), see column 3, lines 50-57. Pinchuk et al. teach the use of barrier layers which coat the copolymers of the invention in order to retard diffusion of the therapeutic agent and prevent a burst phenomenon, see column 16, lines 54-67. Pinchuk et al. teach the use of elastomeric and thermoplastic blocks, see column 1, lines 54-55.

Pinchuk et al. does not expressly teach wherein the elastomeric block comprises dimethylpolysiloxane.

Smith et al. teach thermoplastic block copolymers having methylstyrene end blocks and polydimethylsiloxane (elastomeric) intermediate blocks. Smith teaches that the elastomeric materials are useful for medical and therapeutic device applications, see abstract.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate the elastomeric blocks of polydimethylsiloxane with the thermoplastic blocks taught by Pinchuk et al. One would have been motivated to do so because it is taught by Smith et al. that such block copolymers are said to contain good strength and resistance to tearing, see column 5, lines 3-4. There would have been a reasonable expectation of success because Pinchuk et al. teach combining thermoplastic blocks including methylstyrene or styrene with elastomeric blocks. Furthermore, both references disclose using block copolymers for medical device applications. Regarding the elongation of break of at least 25% at ambient temperature, and the rubbery and hard phases of the polymers, these are considered a property of

the block copolymer claimed. As the combined teachings of Pinchuk and Smith teach the structural block copolymer (elastomeric and thermoplastic blocks) it is expected that the block copolymer exhibits the same properties as the claimed invention. Furthermore MPEP 2112.01 recites if the composition is physically the same, it must have the same properties.

Neither Pinchuk nor Smith disclose sterilization of the device by radiation, however sterilization is an inherent property to any medical device which are inserted into the body. Furthermore, as disclosed by Hamilton et al. thermoplastic elastomers for medical devices are resistant to radiation, thus enable them to be sterilized by radiation, see column 3, lines 54-62.

RESPONSE TO REMARKS

Applicants argue that the materials described in Smith which incorporates Kaeble by reference are directed towards sealing materials. Sealing materials, while useful for many medical applications are clearly inappropriate for forming polymeric carrier regions like those claimed which comprise a therapeutic agent and which release the therapeutic agent upon administration to a patient, thus the art teaches away.

In response, the Examiner respectfully submits that Smith et al. teach that the elastomer compositions disclosed are for use in medical and therapeutic device applications, see abstract. While Smith et al. does not expressly disclose a stent, it would have been within the purview of one of ordinary skill in the art to arrive at the instant invention through the teachings of Pinchuk and Smith because Smith teaches that the elastomer block polymers disclosed are useful for therapeutic and medical devices. Furthermore, Smith expressly teaches that such block copolymers contain good strength and resistance to tearing, see column 5, lines 3-4. Therefore one would have been motivated to use the polymers disclosed in Smith which already teaches

medical device applications, with the medical devices of Pinchuk as they provide good strength and resistance to tearing and are capable of being used with medical device applications. One would expect that polymeric carrier regions which contain a therapeutic agent would need to impart good strength and resistance to tearing on medical devices so that the drugs do not get released prematurely. Therefore, the Examiner respectfully submits that the polymers disclosed in Smith et al. for medical device applications are necessarily capable of being applied as carriers for medical devices.

CONCLUSION

Applicant's arguments/remarks are considered unpersuasive. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Sarah Al-Awadi whose telephone number is (571) 270-7678. The examiner can normally be reached on 9:30 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bonnie Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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